K080591 p. 1 of 2

NOV 14 2008

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by:
Pharos Life Corporation
11-380 Jamieson Parkway
Cambridge, Ontario
N3C 4N4

1. **Date Prepared:**
February 26, 2008

2. **Contact Person:**

Phil Cuscuna
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3. **Device Name and Classification:**

Trade Name:	Tända Skincare System
Common Name:	Tända Skincare System
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Panel:	General & Plastic Surgery
CFR Section:	21 CFR §878.4810
Device Class:	Class II
Device Code:	GEX

4. **Intended Use:**
The Tända Skincare System is intended as an over-the-counter phototherapy device for the treatment of mild to moderate acne.

5. **Substantial Equivalence:**

The Tända Skincare System is substantially equivalent to:
- Tända Skincare System, Pharos Life Corp, K070185, (Aug 21, 2007)
- Zeno, Tyrell Inc., K043377, (July 13, 2005)

6. Device Description:

The Tända Skincare System is a modular platform which uses light treatment heads combined with onboard electronic controls and intelligence designed to offer solid state light source treatments for mild to moderate inflammatory acne.

7. Comparison of Technological Differences:

The intended use and technological characteristics of the Tända Skincare System are virtually identical to the combined intended uses and technological characteristics of the listed equivalent devices. Any differences between the Tända Skincare System and the equivalent devices have no significant influence on safety or effectiveness of the Tända product.

8. Additional Safety Data

A clinical Study under the supervision of a Health Care practitioner (MD) was undertaken and shown to demonstrate that the Tända Skincare System can be used safely as a non-prescription device.

The Tända Skincare System has undergone certification to IEC 60601-1. In addition, testing and analysis have demonstrated compliance to ISO 10993 (Biocompatibility).

The ocular hazard level presented by unprotected exposure to the Tända Skincare light source was determine by applying the calculations specified in Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices of the American Conference of Governmental Industrial Hygienists Worldwide and the standards of the International Commission on Non-ionizing Radiation Protection. The results indicate that the Tända Skincare System - does not pose a risk of retinal injury due to either the blue-light phototoxic effect, or the thermal damage mechanism. In addition, there are no negative additive effects from light exposure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2008

Pharos Life Corporation
% Mr. Phil Cuscuna
11-380 Jamieson Parkway
Cambridge, Ontario, Canada
N3C 4N4

Re: K080591
Trade/Device Name: Tända Skincare System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 12, 2008
Received: November 12, 2008

Dear Mr. Cascuna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080591 p 1 of 1

Indications for Use

510(k) Number:

Device Name: **Tända Skincare System**

Indications For Use:

The Tända Skincare System is generally indicated to treat dermatological conditions. Specifically, Blue light modules are indicated to treat mild to moderate inflammatory acne.

Prescription Use	AND/OR	Over-The-Counter Use	X
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080591